IAP20Rec'd PCT/PTO 10 MAY 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: HAHN5

In re Application of:
Sei Kwang HAHN et al.

IA No: PCT/JP2004/016948

IA Filed: November 15, 2004

Appln. No.:
Not yet assigned

For: CROSSLINKED POLYSACCHARIDE)
MICROPARTICLES AND METHOD...

Atty. Docket: HAHN5

Conf. No.:

Art Unit:

Washington, D.C.

May 10, 2006

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents U.S. Patent and Trademark Office Customer Service Window Randolph Building, Mail Stop Amendment 401 Dulany Street Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §\$1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- [X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:
- [X] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- [] B. before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR §1.114; or

- [] C. after (A) and (B) above, but before final rejection or allowance, and Applicant has made the necessary certification (box "i" below) or paid the necessary fee (box "i" below):
 - [] i. Counsel certifies that, upon information and belief, each item of information listed herein either was
 - [] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
 - [] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR \$1.56(c) more than three months prior to the filing of this IDS.
 - [] ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR \$1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.
- [X] 2. In accordance with 37 CFR \$1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR \$1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:

[]	Α.	Documen	t(s		 is/are	deeme	:d
substantially	cum	ulative	to	document(s)	 		and,

in accordance with 37 CFR \$1.98(c), a copy of each of the former document(s) is not enclosed.

[] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications) Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449, PTO/SB/08a and/or PTO/SB/08b (or their BN form equivalents) from the files of the prior application(s) or a fresh BN/SB/08A and/or BN/SB/08B listing these documents, and request that they be considered and made of record in accordance with 37 CFR \$1.98(d). Per 37 CFR \$1.98(d), copies of these documents need not be filed in this application.

- [X] 3. Documents AI, AK, AN-AQ, and AS-AU are not in the English language. In accordance with 37 CFR \$1.98(a)(3), Applicant states:
 - [X] An English translation of each document AI, AK, AN-AQ, and AS-AU (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.
 - [X] For documents AK, AO, AP, AS, and AU, a corresponding English-language patent or published application is included on the accompanying Form BN/SB/08A, with a line drawn in the margin connecting the non-English-language document with its corresponding English-language document.
 - [X] A concise explanation of the relevance of documents AI, AK, AN-AQ, and AS-AU is found in the attached <u>International Search Report</u> (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
 - [] A concise explanation of the relevance of document(s) _____ is set forth as follows:

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[]	A concise explanation	of the relevance of
		document(s)	can be found on page(s)
		of the specif	fication.
[]	A concise explanation	of the relevance of
		document(s)	can be found on the

[X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

attached sheet.

- [] 5. Other information being provided for the examiner's consideration follows:
- In accordance with 37 CFR §\$1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK

Attorneys for Applicant(s

Roger L. Browdy Registration No. 25,618

624 Ninth Street, N.W., Suite 300 Washington, D.C. 20001-5303

Washington, D.C.

Telephone: (202) 628-5197 Facsimile: (202)737-3528

RLB: 1mh

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of

Complete if Known					
Application Number	Not yet assigned				
Filing Date	Even date herewith				
First Named Inventor	Sei Kwang HAHN				
Group Art Unit	AU/5/9U5C				
Examiner Name					
Attorney Docket Number	HAHN5				

	U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (IT} known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
→	AA	US- 587,913 A	08-10-1897	Bates				
-	AB	US- 5,827,937 A	10-27-1998	Agerup				
—	AC	US-2001/0007665 A1	07-12-2001	Illum et al.				
-	AD	US- 6,221,397 B1	04-24-2001	Russell-Jones et al.				
→	AE	US-2002/0197328 A1	12-26-2002	Kim et al.				
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		Foreign Patent Number			Pages, Columns, Lines,	
Examiner Initials*	Cite No.1	Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Publication Date Name of Patentee of Applicant		T ⁶
	AF	WO 95/15168 A1	06-08-1995	The Research Foundation of State Univ. of New York		
	AG	WO 96/18647 A1	06-20-1996	Johnson & Johnson Corp.		
	АН	WO 97/04012 A1	02-06-1997	Agerup	· · · · · · · · · · · · · · · · · · ·	
	Al	JP 9-59303 A	03-04-1997	Shiseido Co. Ltd		ABS
	AJ	WO 97/35562 A1	10-02-1997	Danbiosyst UK Ltd.		
	AK	JP 10-509696 a	09-22-1998	Focal, Inc.		ABS
	AL	WO 98/43664 A1	10-08-1998	LG Chemical Ltd.		
	AM	WO 99/11703 A1	03-11-1999	Biotech Australia Pty. Ltd.	*	
	AN	JP 11-193246 A	07-21-1999	Sumitomo Pharm Co. Ltd.		ABS
→	AO	JP 11-509256 A	08-17-1999	Kyu Medo AB		ABS
	AP	JP 11-513047 A	11-09-1999	LG Chemical Ltd.		ABS
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	AR	WO 00/44808 A1	08-03-2000	Hubbell		
-	AS	JP 2000-5101000 a	08-08-2000	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Ltd.		ABS
	AT	JP 2000-248002 a	09-12-2000	Denki Kagaku Kogyo Kabushiki Kaisha		ABS
 	AU	JP 2001-514316 A	09-11-2001	Biotech Australia Pty Ltd.		ABS

Examiner Signature	Date Considered	*
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^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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					THE PERSON NAMED IN THE PE			
1	Substitute	for form 1449A/PTO			Complete if Known			
					Application Number	Not yet assigned 5 79 132		
	INFO	RMATION D	IS	CLOSURE	Filing Date	Even date herewith		
	STATEMENT BY APPLICANT				First Named Inventor	Sei Kwang HAHN		
					Group Art Unit			
		(use as many sheets	as n	ecessary)	Examiner Name	•		
	Sheet	2	of	2	Attorney Docket Number	HAHN5		

		NON PATENT LITERATURE DOCUMENTS / OTHER INFORMATION	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
	AV	He, P., et al., "Chitosan microspheres prepared by spray drying", International Journal of Pharmaceutics, (1999), Vol. 187, pp. 53-65	
		Stahl, K., et al., "The effect of process variables on the degradation and physical properties of spray dried insulin intended for inhalation", International Journal of Pharmaceuticals, (2002), Vol. 233, pp. 227-237.	
		Surendrakumar, K., et al., "Sustained release of insulin from sodium hyaluronate based dry powder formulations after pulmonary delivery to beagle dogs", Journal of Controlled Release, (2003), Vol. 91, pp. 385-394.	
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Examiner	 Date	
Signature	Considered	

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.